UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PETER G. ANGELOS, Plaintiff v. TOKAI PHARMACEUTICALS, INC., JODIE POPE MORRISON, LEE H. KALOWSKI, SETH L. HARRISON, TIMOTHY J. BABERICH, DAVID A. KESSLER, JOSEPH A. YANCHIK, III, BMO CAPITAL MARKETS CORP., STIFEL, NICOLAUS & COMPANY, INCORPORATED, WILLIAM BLAIR & COMPANY, L.L.C., and JANNEY MONTGOMERY SCOTT LLC, Defendants.	)	C.A. No. 17-11365-MLW

MEMORANDUM AND ORDER

WOLF, D.J. October 9, 2020

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I. SUMMARY

Plaintiff Peter Angelos alleges claims of securities fraud against defendants Tokai Pharmaceuticals, Inc. ("Tokai") and several officers and directors of Tokai (collectively, the "Tokai Defendants"), and BMO Capital Markets Corp., Stifel, Nicolaus & Company, Inc., William Blair & Company, LLC, and Janet Montgomery Scott LLC (collectively, the "Underwriter Defendants").

Tokai was a pharmaceutical company developing an experimental prostate cancer treatment drug called galeterone. Angelos was a major investor in Tokai. He ultimately lost over $10,000,000 on his investments after Tokai announced that it was halting development of galeterone in July 2016, causing the company's shares to lose most of their value.

Angelos alleges that the Tokai Defendants are responsible for materially false and misleading statements and omissions in the Registration Statement for Tokai's 2014 Initial Public Offering

("IPO"), which was underwritten by the Underwriter Defendants. Angelos also alleges that the Tokai Defendants were responsible for materially false and misleading statements and omissions in various public statements following Tokai's IPO.

More specifically, Angelos alleges violations of Section 11 of the Securities Act (Count 1), Section 15 of the Securities Act (Count 3), Section 10(b) of the Exchange Act and Rule 10b-5 (Count 4), and Section 20(a) of the Exchange Act (Count 5).[1] See 15 U.S.C. §§77k(a), 78j(b); 17 C.F.R. §240.10b-5(b).

The Tokai and Underwriter Defendants have separately moved to dismiss the Amended Complaint. As explained below, the court is granting the motions to dismiss because the complaint fails to allege facts sufficient to prove violations of Section 11 or Section 10(b) by the Tokai Defendants and, therefore, the Section 15 and 20 claims against them, and the claims against the Underwriter Defendants must be dismissed as well.

II. THE MOTION TO DISMISS STANDARD

To defeat a motion to dismiss under Rule 12(b)(6) for failure to state a claim upon which relief can be granted, a plaintiff must allege "a plausible entitlement to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007). This means that the complaint

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[1] Plaintiff has agreed to the dismissal of Count 2 of the Amended Complaint, which alleged claims under Section 12 of the Securities Act.

"must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (internal quotations omitted). A claim is facially plausible if the plaintiff pleads "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. at 683. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Id. at 678 (internal quotations omitted).

In considering a motion to dismiss under Rule 12(b)(6), the court must "take all factual allegations as true and . . . draw all reasonable inferences in favor of the plaintiff." Rodriguez Ortiz v. Marao Caribe, Inc., 490 F.3d 92, 96 (1st Cir. 2007). The court "neither weighs the evidence nor rules on the merits because the issue is not whether plaintiffs will ultimately prevail, but whether they are entitled to offer evidence to support their claims." Day v. Fallon Cmty. Health Plan, Inc., 917 F. Supp. 72, 75 (D. Mass. 1996).

Federal Rule of Civil Procedure 9(b) imposes a heightened pleading standard that requires that the plaintiff state "with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To plead circumstances "with particularity," a plaintiff must specify "the who, what, where, and when of the

allegedly false or fraudulent representation." Rodi v. S. New England Sch. Of Law, 389 F.3d 5, 15 (1st Cir. 2004).

"Under Rule 12(b)(6), the district court may properly consider only facts and documents that are part of or incorporated into the complaint." Rivera v. Centro Medico de Turabo, Inc., 575 F.3d 10, 15 (1st Cir. 2009) (quotations omitted); see Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993). However, there are "narrow exceptions for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiff['s] claim; or for documents sufficiently referred to in the complaint." Watterson, 987 F.2d at 3. When "a complaint's factual allegations are expressly linked to -- and admittedly dependent upon -- a document (the authenticity of which is not challenged), that document effectively merges into the pleadings and the trial court can review it in deciding a motion to dismiss under Rule 12(b)(6)." Beddall v. St. Street Bank & Tr. Co., 137 F.3d 12, 17 (1st Cir. 1998). When such documents contradict an allegation in the complaint, the document trumps the allegation. See Clorox Co. P.R. v. Proctor & Gamble Commercial Co., 228 F.3d 24, 32 (1st Cir. 2000) (citing Northern Ind. Gun & Outdoor Shows, Inc. v. City of South Bend, 163 F.3d 449, 454 (7th Cir. 1998)).

III. FACTS

The Amended Complaint (Docket No. 80) alleges the following facts. More detail regarding the particular statements plaintiff

alleges were misleading are included in the below sections that address the alleged misstatements.

Tokai was a developmental stage pharmaceutical company. Since 2008, Tokai had been focused on developing a single medication, galeterone, for metastatic castration-resistant prostate cancer ("CRPC"), a serious form of prostate cancer. Tokai had no other drugs or drug candidates. See Am. Compl. ¶¶31-32. As Tokai had accumulated a significant deficit by the end of 2013, it conducted an IPO to raise funds. Tokai filed a Form S-1A Registration Statement and Prospectus with the Securities and Exchange Commission ("SEC"). It commenced the IPO on September 18, 2014. The IPO raised $105,300,000 for Tokai. See id. ¶33.

To obtain Federal Drug Administration ("FDA") approval, a candidate drug must go through three phases of clinical trials. Phase I studies often involve twenty to eighty subjects and are designed to determine how the drug works in humans. See id. ¶35. Phase II studies usually involve no more than several hundred subjects and are designed to evaluate the effectiveness of the drug. See id. Phase III studies are typically large-scale trials, usually involving several hundred to several thousand subjects, and are intended to gather the information necessary to provide an adequate basis for labeling the drug. See id. ¶35.

The Registration Statement stated that Tokai believed galeterone had advantages over existing CRPC treatments in a

certain subset of patients. See id. ¶37. At the time of the IPO, the galeterone Phase 2 trial was ongoing, but had already reported some promising findings. In particular, the Registration Statement stated that a "retrospective subset analysis" of the Phase 2 data indicated that galeterone was effective in a subset of CRPC patients with DNA exhibiting "truncated androgen receptors as having C-terminal loss", the most common variant of which is known as "AR-V7". See id. ¶¶37-38, 45. The Phase 2 trial had studied galeterone's effectiveness in CRPC patients who had not received other treatment, without regard to whether the patients were AR-V7 positive ("AR-V7+"). See id. ¶55. The Registration Statement noted that two clinical studies had found that two existing CRPC medications, Zytiga and Xtandi, were not effective in AR-V7+ patients. See id. ¶39. By contrast, the retrospective analysis of galeterone's Phase 2 data indicated that it was effective in six out of the seven AR-V7+ patients that were studied. See id. ¶58.

The Registration Statement announced Tokai's intent to pursue a Phase 3 trial studying galeterone's effectiveness in AR-V7+ patients, with the intention of obtaining FDA approval to market the drug to them. See id. ¶41. The Registration Statement reported that Tokai had met with the FDA and, based on these discussions, was planning a Phase 3 trial comparing galeterone to Xtandi in up to 170 AR-V7+ CRPC patients. See id. ¶41. An independent Data Monitoring Committee would oversee the trial and review its

results. See Registration Statement (Docket No. 83-1) (Mot. to Dismiss Ex. 1) at 92.

Tokai had not ever run a Phase 2 trial aimed at testing galeterone's effectiveness in AR-V7+ patients. See Am. Compl. ¶55. Instead, Tokai relied on a retrospective analysis of its more general Phase 2 data to support its belief that galeterone would be effective in AR-V7+ patients. See id. Tokai allegedly decided to shift its focus to AR-V7+ patients shortly before filing the IPO, when it learned of the imminent release of a New England Journal of Medicine article indicating that Zytiga and Xtandi were not effective in these patients. See id. ¶¶55-59.

According to plaintiff, there were several issues concerning the Phase 3 trial proposed in the Registration Statement. Tokai had never conducted a study testing galeterone on AR-V7+ patients specifically, and had never compared it to other medications. See id. ¶55. The planned Phase 3 trial was also much smaller than a typical Phase 3 trial. See id. ¶61. Finally, the Phase 3 trial would measure "radiographic progression free survival" ("rPFS") as an endpoint, while the Phase 2 trial had measured the presence of an antigen linked with prostate cancer.[2] Plaintiff, therefore,

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[2] "Progression-free survival" is "[t]he length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse." Nat'l Cancer Inst., NCI Dictionary of Cancer Terms, available at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/

contends that the Phase 2 trial was so different that its results did not suggest that the planned Phase 3 trial would be successful. See id. ¶¶60-63.

Tokai announced the commencement of the Phase 3 trial in a June 24, 2015 press release, which stated that the trial had been initiated at more than 15 sites and that results were expected by the end of 2016. See id. ¶¶65-69. Tokai's August 2015 Form 10-Q similarly stated that the Phase 3 trial had begun and that Tokai was "comparing galeterone to Xtandi [] in 148 metastatic CRPC patients." Id. ¶73. Tokai reportedly made similar statements in an August 3, 2015 Boston Business Journal Article, and in an August 12, 2015 press release. See id. ¶¶73-76. Tokai's November 2015 Form 10-Q again stated that the Phase 3 trial was underway in approximately 148 patients. See id. ¶78.

In March 2016, Tokai issued a press release indicating that the Phase 3 Trial was screening patients at over 100 clinical test sites. See id. ¶80. It again stated that the trial was ongoing in approximately 148 patients in its 2015 Form 10-K filed in March 2016. See id. On May 10, 2016, a press release stated that Tokai had made "significant progress in our clinical development program for galeterone" and that Tokai had "continued to accelerate screening and enrollment." Id. ¶86.

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progression-free-survival.

Despite these previous optimistic statements, in a July 26, 2016 press release Tokai announced that it was discontinuing the Phase 3 trial. See id. According to Tokai, the committee responsible for monitoring the trial had determined that continuing the trial was futile as it was unlikely to demonstrate an improvement in the survival rate for AR-V7+ CRPC patients treated with galeterone as compared to Xtandi. See id. ¶86. In Tokai's next Form 10-Q, it announced that it would probably not pursue development of galeterone for AR-V7+ patients and was eliminating 60% of its workforce. See id. ¶88.

Angelos had purchased shares of Tokai stock at various times between December 8, 2014 and November 3, 2015. See Docket No. 80-1. Following Tokai's announcement of the cancellation of the Phase 3 trial, the price of a Tokai share fell from $5.20 to $1.10. See id. ¶89. Angelos sold all of his remaining holdings in Tokai following announcement of the cancellation of the Phase 3 trial. See id. ¶¶89-90. He lost more than $10,000,000, which was more than 90% of his investment. See id.

The reasons for the termination of the Phase 3 study were revealed in a Journal of Clinical Oncology ("JCO") article published in May 2017, almost a year after Tokai announced the study's cancellation. See Am. Compl. ¶92; JCO article abstract (Mot. to Dismiss Ex. 19) (Docket No. 93-1). The JCO article abstract states that 953 patients were screened, 73 were AR-V7+,

38 were randomized into the study, 31 had "screen failed", and 4 were discontinued from screening when the study ended, indicating that the trial was well below its planned enrollment of 148 patients. See Am. Compl. ¶92. The preliminary results of the halted study also indicated that galeterone was less effective than Xtandi in AR-V7+ patients, achieving favorable results in 13% (2/16) of patients compared to 41% (8/19) for Xtandi. See id. Tokai itself never disclosed these results. See id. ¶93.

Plaintiff contends that the disclosure of these results revealed that many of Tokai's prior statements concerning the trial were materially misleading if not false. See id. ¶¶9, 50, 92. Plaintiff focuses particularly on Tokai's failure to disclose that the study was failing to recruit an adequate number of test subjects. See id. ¶155.

IV. PROCEDURAL HISTORY

This case was originally consolidated for pretrial purposes with two putative class actions brought under the Private Securities Litigation Reform Act ("PSLRA"), Garbowski v. Tokai, C.A. No. 16-11963, and Doshi v. Tokai, C.A. No. 16-11992. Those cases were each voluntarily dismissed after the proposed lead plaintiff withdrew his motion to serve as lead plaintiff. See Garbowski v. Tokai Pharm., Inc., 302 F. Supp. 3d 441, 444 (D. Mass. 2018). A third related class action, Wu v. Tokai, C.A. No. 16-cv-12550, was remanded to Massachusetts state court after the Supreme

Court decided Cyan, Inc. v. Beaver Cty. Employees Ret. Fund, 138 S. Ct. 1061 (2018).

Angelos, suing on his behalf only, filed his Complaint on July 25, 2017. See Docket No. 1. Following the dismissal and remand of the related actions, Angelos filed an Amended Complaint on September 7, 2018. See Docket No. 80. The Tokai and Underwriter Defendants have moved to dismiss the Amended Complaint. See Docket Nos. 81, 85.

V. PLAINTIFF HAS NOT STATED A PLAUSIBLE CLAIM THAT THE REGISTRATION STATEMENT VIOLATED SECTION 11 OF THE SECURITIES ACT.

Count 1 alleges that the Registration Statement violated Section 11 of the Securities Act. See Am. Compl. ¶¶112-119. "Section 11 of the Securities Act creates a cause of action based on a registration statement that 'contain[s] an untrue statement of a material fact or omit[s] . . . a material fact required to be stated therein or necessary to make the statements therein not misleading.' 15 U.S.C. §77k(a)." Yan v. ReWalk Robotics Ltd., 973 F.3d 22, 31 (1st Cir. 2020); Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund, 575 U.S. 175, 179 (2015).

Section 11 creates "virtually strict liability for any 'untrue statement' or misleading omission of material fact in a registration statement." In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 755 (1st Cir. 2016). "An issuer is strictly liable under a Section 11 claim, while officers, directors and underwriters may

raise the affirmative defense of reasonable investigation." Lenartz v. Am. Superconductor Corp., 879 F. Supp. 2d 167, 187 (D. Mass. 2012). Unlike claims under Section 10(b) of the Exchange Act, to prevail on a Section 11 claim a plaintiff does not need to prove a defendant acted with scienter, the "intent to deceive or defraud." Omnicare, 575 U.S. at 179.

"[W]hether a statement is 'misleading' depends on the perspective of a reasonable investor: The inquiry (like the one into materiality) is objective." Id. at 186-87. "A fact is material when there is 'a substantial likelihood' that a reasonable investor would have viewed it as 'significantly alter[ing]' the 'total mix' of information made available." City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 756 (1st Cir. 2011) (quoting Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)). "A statement can be 'false or incomplete' but not actionable 'if the misrepresented fact is otherwise insignificant.'" Id. at 756-57 (quoting Basic, 485 U.S. 224 at 238).[3]

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[3] The Underwriter Defendants contend that Federal Rule of Civil Procedure 9(b)'s heightened pleading standards apply to plaintiff's Section 11 claims because they "sound in fraud" notwithstanding the Amended Complaint's general statement that the Section 11 claims "do not sound in fraud." Am. Compl. ¶113; see In re Sonus Networks, Inc. Sec. Litig., 2006 WL 1308165, at *5 (D. Mass. May 10, 2006) ("Claims under Sections 11 and 12(a)(2) of the Securities Act that 'sound in fraud' also trigger the pleading requirements of Rule 9(b)."). As the court finds that the Amended

The Amended Complaint alleges numerous purported misrepresentations and omissions in Tokai's Registration Statement.

However, the court finds that the Amended Complaint fails to state a claim for a violation of Section 11 because the alleged false statements or omissions at issue could not be found to have been material to a reasonable investor in light of the totality of information disclosed in the Registration Statement. See Waters Corp., 632 F.3d at 756. More specifically, the Registration Statement adequately disclosed the many potential risks inherent in the Phase 3 Trial as well as the Tokai Defendants' basis for their hope that it would succeed. Therefore, the court is dismissing plaintiff's Section 11 claims.

Plaintiff argues that the Registration Statement's disclosures regarding the existing CRPC treatments, Xtandi and Zytiga, were misleading. See, e.g., Feb. 18, 2020 Tr. at 26. More specifically, the Amended Complaint alleges that it was materially misleading for the Registration Statement to state that these drugs had combined sales of over $2.1 billion in 2013, without disclosing that the Phase 3 trials for each of the drugs had about 1,200 patients each, which is typical of a Phase 3 trial and much more

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Complaint fails to adequately allege any material misstatements or omissions in the Registration Statement, it is unnecessary to resolve this issue.

than the planned up to 170-patient galeterone Phase 3 study described in the Registration Statement. See Am. Compl. ¶¶43-44.[4] According to plaintiff, this omission would have led a reasonable investor to conclude that the Phase 3 trial for galeterone would be of a similar size. See Sur-Reply (Dkt. No. 94) at 17.

At the hearing on the motions to dismiss, plaintiff also argued that it was misleading for the Registration Statement to note the $2.1 billion market for the existing drugs as there was "no basis" to suggest that galeterone would take a significant portion of this market or compete with them. See Feb. 18, 2020 Tr. at 25. Plaintiff asserts that the eventual results of the Phase 3 trial indicate that AR-V7+ patients are rare and the size of the market for a drug targeting such patients would be significantly less than $2.1 billion. See Feb. 18, 2020 Tr. at 24-25.

The plaintiff does not plausibly allege that the failure to include the foregoing information was misleading, or in any event material, in light of the information that was disclosed. See Waters Corp., 632 F.3d at 756; In re Keryx Biopharmaceuticals,

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[4] It appears that the Phase 3 trial size of Xtandi was disclosed in a Form 8-K filed by its parent company, and that the Phase 3 trial size for Zytiga could be located on www.clinicaltrials.gov. See Mem. Supp. Tokai Mot. Dismiss at 9, n.3; Exs. 12-15. The parties dispute whether or not this information would already have been known by a reasonable investor in light of the fact that it could be uncovered from publicly available documents. The court assumes, without finding, that reasonable investors would not be aware of the size of clinical trials for Xtandi and Zytiga.

Inc., Sec. Litig., 2014 WL 585658, at *10 (S.D.N.Y. Feb. 14, 2014) ("An actionable omission must be information that, in light of other statements made, defendants had a duty to disclose so as not to mislead."). The size of the planned Tokai Phase 3 trial -- up to 170 patients -- was accurately disclosed numerous times in the Registration Statement. See, e.g., Reg. Statement at 2, 5, 16, 76, 78, 91. Therefore, it is not plausible that a reasonable investor would have been misled into thinking that galeterone's Phase 3 trial would involve the several hundred to several thousand patients usually included in a Phase 3 trial. See, e.g., N.J. Carpenters Pens. Ann. Fund v. Biogen Idec, Inc., 537 F.3d 35, 39 (1st Cir. 2008) ("Phase III studies are large-scale trials, usually involving several hundred to several thousand subjects . . . ."). Moreover, additional information regarding the sizes of the Phase 3 trials of competing drugs would not have been material to a reasonable investor because the size and methodology of Tokai's Phase 3 trial was properly disclosed in the Registration Statement. See Gregory v. ProNAi Therapeutics Inc., 297 F. Supp. 3d 372, 411 (S.D.N.Y. 2018) ("Whatever plaintiffs' critique of the design of ProNAi's studies, plaintiffs cannot claim that these amply disclosed design features were kept from the public.").

Plaintiff does not identify any representations in the Registration Statement regarding the size of the market for galeterone or any statements that a reasonable investor could

construe as representing that the market for galeterone would be comparable to the $2.1 billion market for Zytiga and Xtandi. Rather, the Registration Statement stated that the market Tokai was targeting consisted of only a "small percentage of CRPC patients," the market being treated by Xtandi and Zytiga, and that the prevalence of AR-V7+ was "subject to widely varying projections in published literature." Reg. Statement at 19, 20. Therefore, it is not plausible that the Registration Statement's mention of the $2.1 billion market for Zytiga and Xtandi could be found to be misleading.

Plaintiff also argues that the Registration Statement misrepresented two studies of Zytiga and Xtandi to suggest that galeterone would likely be more effective for AR-V7+ patients. See Feb. 18, 2020 Tr. at 21. In addition, plaintiff alleges that Tokai made a last-minute decision to focus its clinical development of galeterone on AR-V7+ patients when it learned of a forthcoming article finding that those drugs were ineffective in AR-V7+ patients. See Am. Compl. ¶59.

The Registration Statement notes that "[i]n clinical studies conducted by researchers at MD Anderson Cancer Center and Johns Hopkins University, the presence in patients of truncated androgen receptors with C-terminal loss and AR-V7+ was associated with poor responsiveness of patients' prostate tumors to treatment with Zytiga® . . . and Xtandi® . . . ." Am. Compl. ¶40. Plaintiff argues

that the Registration Statement should have disclosed that the leaders of these studies had stated that these findings were based on small trials that may not have been reliable. See id. ¶¶39-40. According to plaintiff, the ineffectiveness of Zytiga and Xtandi in AR-V7+ patients was essential to Tokai's "investment thesis" that there was a significant market for a CRPC treatment for these patients. See id. ¶43. The court assumes, for present purposes, that the facts that the studies of Zytiga and Xtandi were based on small samples and were preliminary could have been material to a reasonable investor.

However, the claim that the Registration Statement did not adequately disclose these facts is not plausible because statements are not actionable where "[t]he total mix of available information included the very information plaintiffs claim was concealed." In re Merrill Lynch Auction Rate Sec. Litig., 704 F. Supp. 2d 378, 397 (S.D.N.Y. 2010), aff'd sub nom. Wilson v. Merrill Lynch & Co., 671 F.3d 120 (2d Cir. 2011) (quotations omitted).

While not mentioned in the "Overview" section of the Registration Statement where the studies of Zytiga and Xtandi are first discussed, the Registration Statement later discloses their preliminary nature and the risks of drawing conclusions from them. More specifically, the Registration Statement states that:

> [T]he clinical studies conducted by MD Anderson and Johns Hopkins only involved a limited number of patients with C-terminal loss or AR-V7 and were conducted in

> different patient populations, using different protocols and using different and unvalidated assays to identify patients with C-terminal loss or AR-V7. . . . The outcome of preclinical testing and clinical studies may not be predictive of the success of later clinical trials and is often susceptible to varying interpretations and analyses. If Zytiga and Xtandi are found to be more responsive to C-terminal loss or AR-V7 than we anticipate, any clinical trial designed to compare galeterone to Zytiga and Xtandi for this patient population would be less likely to succeed.

Reg. Statement at 18-19 (emphasis added). It goes on to state that while "[w]e believe that these data [the Tokai retrospective study and the study of Zytiga and Xtandi quoted above] support our view that galeterone may be effective" in AR-V7+ patients, "there can no assurance that these data will be predictive of the success" of the Phase 3 trial. Id. at 19. In light of these specific statements, it is not plausible that a reasonable investor would have received from the Registration Statement the misleading impression that the finding of studies that Xtandi and Zytiga were ineffective in AR-V7+ patients was based on large studies or conclusive.

Plaintiff next alleges that the Registration Statement was materially misleading because it selectively disclosed Tokai's discussions with the FDA. This claim is also not plausible.

The Registration Statement states that "[b]ased on [Tokai's] discussions with the FDA," the planned Phase 3 trial would "be a randomized, open label clinical trial comparing galeterone to Xtandi in up to 170 metastatic CRPC treatment-naïve patients whose

prostate tumors express the AR-V7 splice variant." Reg. Statement at 16. Plaintiff asserts that Tokai did not disclose the criteria for eligibility to be studied that was so limiting that it would be unable to recruit a sufficient number of patients for the study. See id. ¶42. Without identifying any evidence of discussions with the FDA on this subject, plaintiff asserts that Tokai must have discussed it with the FDA because relatively few patients ultimately qualified for the study. See id. ¶128.

The disclosure of positive FDA feedback without also disclosing relevant negative or cautionary feedback could in some circumstances constitute a material omission. See, e.g., Frater v. Hemispherx Biopharma, Inc., 996 F. Supp. 2d 335, 346 (E.D. Pa. 2014). However, plaintiff does not allege facts that would support a plausible inference that the FDA provided any negative or cautionary feedback to Tokai. See id. As indicated earlier, the Registration Statement stated that Tokai would seek to compare the effectiveness of galeterone and Xtandi in up to 170 AR-V7+ patients. Reg. Statement at 16. The JCO article discussing the results of the truncated trial, which is referenced in the Amended Complaint, see Am. Compl. ¶92, supports the conclusion that Tokai attempted to do this.

The JCO article explains that 953 patients were screened for admission into the study. 73 men were identified as AR-V7+. Of these 73, 38 were randomized into the study, 31 "screen failed"

(meaning they did not meet the criteria for inclusion into the study), and 4 were discontinued from screening when the study was cancelled. See JCO article (Docket No. 93-1). As indicated earlier, the Registration Statement describes several criteria for admission into the study. A patient must: 1) have metastatic CRPC; 2) have the AR-V7 genetic variation; and 3) not have undergone any other CRPC treatment. See Reg. Statement at 16. There is no basis for an allegation that any other exclusion criteria were applied in the study. Therefore, the contention that the FDA prompted Tokai to utilize undisclosed exclusion criteria, or provided Tokai any relevant negative feedback, is merely speculative and not plausible. See Iqbal, 556 U.S. at 683; Cody v. Conformis, Inc., 199 F.Supp.3d 409, 418 (D. Mass. 2016).

As explained earlier, the Registration Statement detailed the results of a retrospective subset analysis which found that galeterone had been effective in six out of seven identified AR-V7+ patients from Tokai's Phase 2 trial. Plaintiff contends it was materially misleading for the Registration Statement to not disclose that six of the eight individuals that conducted this study had financial ties to Tokai. See Am. Compl. at ¶¶45-49; Reg. Statement at 2-3.

However, plaintiff does not allege that the findings of the retrospective study were not true or that the researchers were paid to reach a certain conclusion. In In re Milestone Sci. Sec.

Litig., 103 F. Supp. 2d 425, 455 (D.N.J. 2000), the court held that the failure to disclose the compensation of authors of positive articles on the defendant company's product, which the company cited in SEC filings, was not material where the plaintiff did not allege that the authors "published anything other than truthful findings" or were paid for the articles. This is equally true in the instant case.

Finally, plaintiff also alleges that the Registration Statement was misleading because it failed to disclose that the proposed galeterone Phase 3 trial was doomed to fail because of numerous issues with its design. See Am. Compl. ¶54. More specifically, plaintiff alleges that Tokai had never conducted a study testing galeterone on AR-V7+ patients and had never compared it to other medications, as the Phase 2 trial had evaluated galeterone as a stand-alone drug in CRPC patients generally. See id. ¶55. Further, the Phase 2 trial had measured the presence of an antigen linked with prostate cancer as an endpoint, while the Phase 3 trial endpoint would be "radiographic progression free survival". It is alleged that the approach of the Phase 3 trial was, therefore, so far afield from that of the Phase 2 trial that the Phase 2 results did not suggest Phase 3 would succeed. See id. ¶¶60-62. The plaintiff also contends that the planned Phase 3 trial involved only 170 patients, while, as discussed earlier, a typical Phase 3 trial involves 300 to 3000, and the Phase 3 trials

for Xtandi and Zytiga had involved about 1,200 each. See id. ¶62. In addition, plaintiff alleges that two successful trials are typically required to obtain FDA approval for a drug, but Tokai was planning only one. See id. ¶61.

In light of these alleged inadequacies, plaintiff asserts that the statement of risks in the Registration Statement were materially misleading. Plaintiff claims that the Registration Statement should instead have disclosed that "galeterone had no reasonable chance of being approved by the FDA." Compl. ¶54 (emphasis in original).

In essence, plaintiff argues that the planned Phase 3 trial was fatally flawed from the outset. However, the design of the study was fully disclosed in the Registration Statement. See Mem. Supp. Tokai Mot. Dismiss at 8; Reg. Statement at 2, 16, 19; ProNAi, 297 F. Supp. at 411 ("Whatever plaintiffs' critique of the design of ProNAi's studies, plaintiffs cannot claim that these amply disclosed design features were kept from the public."). The research supporting the design of the planned Phase 3 trial, and the reasons why Tokai believed that this design presented an opportunity to capture a significant market that was not being served by existing medications were described. The Registration Statement also disclosed many risks inherent in Tokai's approach, including that existing research "only involved a limited number of patients with C-terminal loss or AR-V7," Reg. Statement at 18,

with AR-V7, and that Tokai had "no experience recruiting patients with AR-V7 for a clinical trial and the percentage of CRPC patients with AR-V7 is subject to widely varying projections," id. at 20. In bold type, the Registration Statement also stated that "[i]f we experience delays or difficulties in the enrollment of patients in our clinical trials . . . our receipt of necessary regulatory approvals might be delayed or prevented." Id. at 19. In addition, the Registration Statement said that "[i]f Zytiga and Xtandi are found to be more [effective for] AR-V7 than we anticipate, any clinical trial designed to compare galeterone to Zytiga and Xtandi for this patient population would be less likely to succeed." Id.

Accordingly, when viewed in the context of the totality of the Registration Statement, see Waters Corp., 632 F.3d at 756, plaintiff has not alleged a plausible claim that any purported misstatement or omission was material. Therefore, the motion to dismiss his Section 11 claims is meritorious.

In view of the foregoing, plaintiff has not alleged a plausible claim that the Registration Statement violated Section 11.

VI. PLAINTIFF HAS NOT STATED A PLAUSIBLE CLAIM THAT TOKAI'S STATEMENTS AFTER THE IPO VIOLATED SECTION 10(b).

Plaintiff alleges violations of Section 10(b) and Rule 10b-5 against the Tokai Defendants only. These allegations address several allegedly misleading statements and omissions made after

the IPO. Since these statements were not in the Registration Statement, there is no potential Section 11 liability for them. See Shaw v. Dig. Equip. Corp., 82 F.3d 1194, 1204 (1st Cir. 1996) (superseded by statute on other grounds). This is significant because, unlike a Section 11 claim, a plaintiff must allege a strong inference of scienter to plead a plausible Section 10(b) claim.

While the court has doubts that plaintiff has adequately alleged any material misrepresentations, the court is dismissing plaintiff's Section 10(b) claims because plaintiff has failed to plead a strong inference of scienter.

Section 10(b) of the Securities Exchange Act "forbids the 'use or employ, in connection with the purchase or sale of any security . . . , [of] any manipulative or deceptive device.'" Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 318 (2007) (quoting 15 U.S.C. § 78j(b)). Pursuant to this statute, SEC Rule 10b-5 makes it unlawful to, among other things, "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. §240.10b-5(b).

"To state a claim for securities fraud under Section 10(b), a plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) in

connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." Fire & Police Pension Ass'n of Colorado v. Abiomed, Inc., 778 F.3d 228, 240 (1st Cir. 2015).

"The PSLRA requires a securities fraud complaint to specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." Id. As explained earlier, "[a] fact is material when there is 'a substantial likelihood' that a reasonable investor would have viewed it as 'significantly alter[ing]' the 'total mix' of information made available." Waters Corp., 632 F.3d at 756 (quoting Basic, 485 U.S. at 231-32). "A statement can be false or incomplete but not actionable if the misrepresented fact is otherwise insignificant." Id. at 756-57.

"Scienter is a 'mental state embracing intent to deceive, manipulate, or defraud.'" Waters Corp., 632 F.3d at 757. "The scienter element may be satisfied by showing that the defendant engaged in 'intentional or willful conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities,'" or that the defendant acted "with a high degree of recklessness." Id. (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 199 (1976)).

"The PSLRA also separately imposes a rigorous pleading standard on allegations of scienter." ACA Fin. Guaranty Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). A complaint will

survive a motion to dismiss only if it states with particularity facts giving rise to a "strong inference" that defendants acted with a conscious intent "to deceive or defraud investors by controlling or artificially affecting the price of securities" or "acted with a high degree of recklessness." Abiomed, 778 F.3d at 240. "[S]cienter should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations." ACA Fin., 512 F.3d at 59. An inference of scienter is "strong" if "a reasonable person would deem [it] cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324. However, a plaintiff "need not plead facts that directly show scienter." ReWalk, 973 F.3d at 39.

i. Plaintiff Does Not Have Standing To Bring Claims Based On Statements Made After His Last Purchase Of Tokai Stock

A plaintiff asserting Section 10 claims only "has standing to assert claims based on activity prior to the date [he] purchased [his] stock." Winer Family Tr. v. Queen, 503 F.3d 319, 325 (3d Cir. 2007); ReWalk, 973 F.3d at 35 (same). Nor can a plaintiff allege a Section 10(b) violation by claiming that they were induced to hold, rather than purchase or sell, stock by misrepresentations. See Winer Family Tr., 503 F.3d at 325 ("There is no private right of action under Rule 10b-5 for mere holders of securities."). Therefore, plaintiff lacks standing to assert Section 10(b) claims

based on statements made by the Tokai Defendants after his final purchases of Tokai stock on November 3, 2015.

This does not mean, however, that statements made by the Tokai Defendants after this date are necessarily irrelevant to the analysis of plaintiff's Section 10(b) claims. Plaintiff argues that statements made after his final purchases of Tokai stock are evidence of scienter, even though these statements could not themselves serve as the basis of a Section 10 violation. See Feb. 18, 2020 Tr. at 87-89. It is true that, in certain circumstances, statements made after a purchase of stock could be evidence of the required scienter prior to that transaction. See, e.g., United States v. Fields, 871 F.2d 188, 197 (1st Cir. 1989) ("Evidence of a conspirator's post conspiracy activity is admissible if probative of the existence of a conspiracy or the participation of an alleged conspirator, even though they might have occurred after the conspiracy ended."); Solow v. Citigroup, Inc., 827 F. Supp. 2d 280, 291 (S.D.N.Y. 2011) ("Post-purchase events have been considered as evidence of scienter.").[5]

The court has, therefore, considered the Tokai Defendants' statements after November 3, 2015 for the limited purpose of deciding whether the alleged facts create the necessary strong

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[5] A post-purchase statement would be evidence of scienter if, for example, a defendant said, "I knew my statement was false when I made it."

inference of scienter concerning the statements made prior to November 3, 2015. However, rather than providing evidence of defendants' intentions or knowledge when they made the statements on which plaintiff can rely, their later statements at most reiterate the alleged misrepresentations in their earlier statements. They, therefore, have little, if any, probative value concerning whether defendants acted with scienter prior to November 3, 2015.

ii. Plaintiff Has Failed To Allege A Strong Inference That The Tokai Defendants Acted With Scienter

Plaintiff alleges that the Tokai Defendants made numerous statements following the IPO that were materially misleading. Most of the statements quoted in the Amended Complaint concern the status of the Phase 3 trial. For example, a June 24, 2015 press release announced that the Phase 3 trial was "on track to read out by the end of 2016." Am. Compl. ¶65. Several public statements mentioned a 148-patient Phase 3 trial.[6] See id. ¶¶73-76. Plaintiff notes Tokai's filings regarding the Phase 3 trial on www.clinicaltrials.gov, a public database of clinical trial results. On the page for the galeterone Phase 3 trial, Tokai represented that from the trial's commencement in June 2015 until

[6] It is not clear why Tokai was seeking to recruit 148 patients instead of the 170 stated in the Registration Statement. The court does not find this discrepancy to be material.

August 2016 enrollment in the Study was "148 (Anticipated)" and that the study was "Recruiting" patients. See id. ¶102.

Plaintiff argues that these statements were misleading as a reasonable investor would have believed that Tokai had already recruited 148 patients or that the trial was on track. See, e.g., Opp'n to Mot. Dismiss (Docket No. 88) at 12. Plaintiff also contends that that the June 24, 2015 press release quoted a doctor without disclosing her financial affiliation with Tokai. See id. ¶66. He also asserts that a January 12, 2015 Tokai press release cited research indicating that existing CRPC medications were ineffective in AR-V7+ patients without stating that these findings were preliminary. See id. ¶70.[7]

It is doubtful that any of the statements on which plaintiff relies could be found to be materially misleading. With one exception, all of the statements regarding the status of the trial also included language that indicated that recruitment had yet to begin or was ongoing. See, e.g., August 12, 2015 10-Q (Docket No.

[7] The complaint also cites an August 28, 2015 press release in which Tokai stated that "[i]nterim data" from the ongoing Phase 2 trial indicated that galeterone was effective in 6 out of 7 AR-V7+ CRPC patients. Am. Compl. ¶71. Plaintiff alleges that this statement was misleading as it did not disclose that "the leaders of these studies found them to be preliminary." Id. It is not clear where or when the leaders of this study, as opposed to the two studies discussed earlier, stated that it was preliminary. In any event, the court finds that this statement was not misleading as the term "interim data" communicates that it is "preliminary".

83-2) at 14 ("Implementation of the clinical trial assay is ongoing and screening of eligible patients is expected to begin this quarter."); June 24, 2015 press release (Docket No. 83-18) ("[S]creening of eligible patients for the splice variant is expected to begin in July [2015]."). Similarly, Tokai's www.clinicaltrials.gov filings indicated at all relevant times that 148 patients were "anticipated" and that recruitment was "ongoing". See Docket No. 83-4. Even if the statements quoted in the complaint could suggest that Tokai had already recruited 148 patients when read in isolation, these other statements in the same documents would have alerted a reasonable investor to the fact that Tokai had not yet finished recruiting patients.

An August 3, 2015 Boston Business Journal article states, without quotation marks, that Tokai Chief Executive Officer Jodie Morrison said that "the 148-patient Phase 3 trial is underway." Dkt. No. 112-2. Viewed in isolation, the statement attributed to Morrison could, arguably, be materially misleading. However, nine days later Tokai stated in a Form 10-Q filed with the SEC that "screening of eligible patients is expected to begin this quarter." August 12, 2015 Form 10-Q (Docket No. 83-2) at 14. This later statement would have dispelled any impression caused by the August 3, 2015 article that Tokai had already recruited 148 patients. Plaintiff did not purchase Tokai stock between August 3 and August 12, 2015. See Stock Purchase Exhibit (Docket No. 80-1). Therefore,

a reasonable investor in his situation could not have reasonably relied on, and been misled by, the statement attributed to Morrison in the August 3, 2015 article.

In any event, as explained earlier, to state a plausible Section 10 claim, plaintiff must plead sufficient facts to support a strong inference of scienter. See Abiomed, 778 F.3d at 240. This means that the inference of scienter must be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324. "[W]hen the facts as a whole more plausibly suggest that the defendant acted innocently—or even negligently—rather than with intent or severe recklessness, the action must be dismissed." Cozzarelli v. Inspire Pharm. Inc., 549 F.3d 618, 624 (4th Cir. 2008). In essence, plaintiff must allege facts supporting a strong inference that at the time defendants made the alleged misrepresentations they either knew them to be false or were at least reckless in making them.

Judge Douglas Woodlock has accurately enumerated factors that the First Circuit has found to support an inference of scienter. These are:

- "insider trading in conjunction with false or misleading statements";
- "a divergence between internal reports and public statements";
- "disclosure of inconsistent information shortly after

the making of a fraudulent statement or omission";

- "bribery by top company officials";
- "evidence of an ancillary lawsuit, charging fraud, which was quickly settled";
- "disregard of current factual information acquired prior to the statement at issue";
- "accounting shenanigans";
- "evidence of actions taken solely out of self-interest";
- "significant GAAP violations"; and
- "motive and opportunity."

In re Sonus Networks, 2006 WL 1308165, at *12-13 (quoting Geffon v. Micrion Corp., 249 F.3d 29, 36 (1st Cir. 2001)). Consideration of these factors in this case indicates that plaintiff has failed to allege the required strong inference of scienter.

Plaintiff argues that defendants knew that the statements at issue were materially false and misleading. He notes stock sales by insiders following the IPO, see Am. Compl. ¶105, and the "critical role" that the success of galeterone played in Tokai's continued viability, id. ¶¶97-98, and asserts that some of the alleged misstatements were so "glaring" that they must have been made with fraudulent intent, id. ¶¶99-100.

As explained earlier, certain post-IPO statements that plaintiff claims are misleading are either accurate or are not misleading in the context of the entire document that contains

them. Even assuming, without finding, that some of these statements could constitute material misrepresentations, however, plaintiff's allegations fail to create a strong inference that any of them were known to be false or misleading or were made with reckless disregard for the truth.

"In cases where [the First Circuit has] found [scienter], the complaint often contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 31 (1st Cir. 2012). There are no such allegations in this case. For example, there are no allegations of any internal reports or communications indicating that defendants knew of problems with the Phase 3 trial when the allegedly misleading statements were made, or of any discussions in which defendants expressed an intent to mislead investors about the Phase 3 trial.

Instead, plaintiff argues that because far fewer than 148 patients enrolled in the Phase 3 study before it was terminated, the defendants must have known at the time they made public statements that the trial was not going to meet its goals. Although Tokai's plan to recruit 148 subjects was unsuccessful, this is not sufficient to prove that "the statements the Company made regarding

the [Phase 3] trial were known to be false at the time they were made." Keryx, 2014 WL 585658, at *13 (S.D.N.Y. Feb. 14, 2014) (emphasis in original); see also In re Ariad, 842 F.3d at 754 ("Because the complaint fails to indicate when the adverse events occurred, let alone when the defendants became aware of them, it fails to create a strong inference of scienter.").

The last statements on which plaintiff could have relied when making his final purchase of Tokai stock in November 2015 were made in August 2015. The Phase 3 trial was terminated in July 2016. Plaintiffs' allegations do not support a strong inference that defendants knew in August 2015 that the trial would fail almost a year later.

The court recognizes that "a plaintiff may combine various facts and circumstances indicating fraudulent intent—including those demonstrating motive and opportunity—to satisfy the scienter requirement." In re Cabletron Sys., Inc., 311 F.3d 11, 39 (1st Cir. 2002) (quotations omitted). "Depending on context, allegations of insider trading may offer some support for inferences of scienter." Waters Corp., 632 F.3d at 760. "Insider trading in suspicious amounts or at suspicious times may be probative of scienter." Mississippi Pub. Employees' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 92 (1st Cir. 2008) However, "'[t]he vitality of the inference to be drawn depends on the facts, and can range from marginal to strong.'" Waters Corp., 632 F.3d at 760

(quoting Greebel v. FTP Software, Inc., 194 F.3d 185, 197-98 (1st Cir. 1999)). For stock sales by corporate officials to bolster an inference of scienter, the trading must be, "[a]t a minimum . . . unusual, well beyond the normal patterns of trading by those defendants." Id. at 761 (quoting Greebel, 194 F.3d at 198).

While the Amended Complaint alleges sales by insiders on certain dates, it does not address the significance of those sales and why they support an inference of scienter. The Amended Complaint includes a chart which lists sales made by defendants Kalowski and Morrison, as well as by John McBride, Tokai's Chief Operating Officer, and Novartis, a venture capital investor in Tokai. See Am. Compl. ¶105. However, the "mere pleading of insider trading, without regard to either context or the strength of the inferences to be drawn, is not enough." Greebel, 194 F.3d at 198. In Abiomed, the First Circuit concluded that no inference of scienter could be drawn from alleged insider sales made by senior executives where, like here, "the complaint [was] silent as to the percentage of holdings sold or the circumstances surrounding the trades." Abiomed, 778 F.3d at 246.

Plaintiff does contend that the timing of the insider sales is suspicious because they occurred around the time of the initiation of the Phase 3 trial in June 2015. The complaint also alleges that many sales occurred in April, July, and September 2015. The last alleged sale occurred in September 2015. See Am.

Compl. ¶105. However, the sales in June 2015 occurred more than a year before the Phase 3 trial failed. Again, it is not reasonable to infer that at or near the outset of the trial defendants expected it would fail and, therefore, had a motive, based on inside information, to sell some of their stock. See Keryx, 2014 WL 585658, at *13 (no inference of scienter from stock sales where "sales did not take place shortly before either the alleged corrective disclosure . . . or . . . when the failure of the Phase 3 trial was announced").

In addition, public filings reveal that the amounts of sales alleged in the complaint were small in comparison to the defendants' holdings. For example, the complaint alleges sales by Novartis that total only around 2% of the shares it held. See Am. Compl. ¶105; Mot. Dismiss Ex. 11 (2015 Proxy) at 30. Similarly, Morrison sold only about 6% of her total holdings. See Am. Compl. ¶105; 2015 Proxy (Mot. Dismiss Ex. 11) (Docket No. 83-11) at 30. See Brennan v. Zafgen, Inc., 853 F.3d 606, 615-16 (1st Cir. 2017) (insider sales were not suspicious where the defendant retained 93% of his shares); Cozzarelli, 549 F.3d at 628 (sales of 13%, 12%, and 3% of insiders' holdings too small to support inference of scienter). Kalowski's sales were more significant as he sold 31.5% of the shares he owned, but some of these were prescheduled sales triggered by the vesting of stock options. See Mot. Dismiss Ex. 8; Ex. 11 at 19-20.

Indeed, the alleged sales by all defendants were made pursuant to 10b-5 trading plans. See Mot. Dismiss Exs. 8-10. As this court has previously written, "[t]he presence of a trading plan rebuts an inference of scienter and supports the reasonable inference that stock sales were pre-scheduled and not suspicious." Stiegele v. Bailey, 2007 WL 4197496, at *13 (D. Mass. Aug. 23, 2007). See also In re Gildan Activewear, Inc. Sec. Litig., 636 F. Supp. 2d 261, 272 (S.D.N.Y. 2009) (10b-5 plan "undermines any allegation that the timing or amounts of the trades was unusual or suspicious"). Plaintiff does not allege that these plans were adopted after defendants knew of problems with the Phase 3 trial to take advantage of an inflated share price. Compare In re Ariad, 842 F.3d at 754 n.6 ("[T]he defendants' use of 10b5-1 trading plans is not dispositive in light of the plaintiffs' allegation that those plans were executed after the beginning of the fraudulent scheme.").

For these reasons, the allegations concerning insider trading do not create or contribute to a strong inference of scienter.

As indicated earlier, plaintiff also alleges that defendants had a motive to "make positive statements about the progress of clinical trials and to omit to disclose negative information" because of the importance of the success of the development of galeterone to Tokai's continued viability. Am. Compl. ¶97. These allegations, however, are similar to "the usual concern by

executives to improve financial results," which the First Circuit has found to be too general to support an inference of scienter without something more. Zafgen, 853 F.3d at 616; see also Cozzarelli, 549 F.3d at 627 ("[T]he motivation[] to raise capital . . . [is] common to every company and thus add[s] little to an inference of fraud."). Such "'catch-all allegations' which merely assert motive and opportunity, without something more, fail to satisfy the PSLRA." In re Cabletron, 311 F.3d at 39 (quotations omitted). Rather, a viable scienter theory based on motive and opportunity "require[s] plausible allegations of concrete benefits that could be realized by the misstatement, and the likely prospect of achieving such benefits." Keryx, 2014 WL 585658, at *8. Plaintiff, however, does not allege that there were any financial incentives or other benefits that the alleged misrepresentations could have helped defendants achieve.

The court has "consider[ed] the complaint in its entirety." Tellabs, 551 U.S at 322. In view of plaintiff's failure to allege direct evidence of scienter or a sufficient motive for defendants to have engaged in fraud, among other things, the court finds that opposing, non-fraudulent inferences for their statements are more plausible than the contention that defendants acted with scienter. See id. at 324.

In essence, Plaintiff's theory is that defendants knew since at least the beginning of the Phase 3 trial that it would be unable

to recruit a sufficient number of patients, yet never informed the public of these difficulties and repeatedly made statements indicating that the trial was on track. In Cozzarelli, the Fourth Circuit found similar allegations that the defendant company knew that it was almost impossible that a Phase 3 trial would succeed yet concealed this information in public statements to be "not even plausible." See 549 F.3d at 627. Because an earlier study had been successful, it was "much more likely that defendants believed [the trial] would succeed than that they thought it would fail." Id.; see also Sapir v. Averback, 2016 WL 554581, at *10 (D.N.J. Feb. 10, 2016) (finding no scienter where "Lead Plaintiffs' theory is that Defendants knew all along that the Phase 3 Studies were unlikely to succeed but concealed this information in order to prolong the viability of the Company.").

In this case the preclinical research and retrospective analysis of the Phase 2 data described in the Registration Statement supported Tokai's approach to the Phase 3 trial. As in Cozzarelli, it is "improbable that [Tokai] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure." 549 F.3d at 627. Rather, it is more likely that defendants believed, or at least sincerely hoped, that the Phase 3 trial would be successful than that they knew it would fail and concealed this fact from investors. Therefore, plaintiff has failed to allege an inference of scienter "cogent and at least

as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324.

Accordingly, the motion to dismiss the Section 10(b) claims is meritorious.

VII. BECAUSE THE COURT HAS FOUND THAT PLAINTIFF HAS NOT STATED PLAUSIBLE SECTION 11 OR SECTION 10 CLAIMS, PLAINTIFF'S SECTION 15 AND SECTION 20 CLAIMS MUST BE DISMISSED

Plaintiff also alleges claims under Section 15 of the Securities Act and Section 20(a) of the Exchange Act. See 15 U.S.C. §77o(a); 15 U.S.C. §78t(a). "The plain terms of section 20(a) indicate that it only creates liability derivative of an underlying securities violation." ACA Fin., 512 F.3d at 67-68. See also Conformis, 199 F. Supp. 3d at 420 ("The Section 11 claim fails to state a claim . . . and concomitantly, so does the Section 15 claim."). As the court has concluded that plaintiff has failed to adequately allege any Section 11 or Section 10(b) violations, plaintiff's Section 15 and Section 20 claims must be dismissed.

VIII. THE CLAIMS AGAINST THE UNDERWRITER DEFENDANTS MUST BE DISMISSED

Plaintiff alleges that the Underwriter Defendants violated Section 11 of the Securities Act, 15 U.S.C. §77k. Because the court has found that plaintiff has failed to adequately allege that the Registration Statement contains any material misstatements or omissions, the claims against the Underwriter Defendants must be dismissed as well. See Shaw, 82 F.3d at 1201 ("Section 11 imposes

liability on . . . underwriters[] if the registration statement 'contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading.'") (quoting 15 U.S.C. §77k)).

IX. ORDER

In view of the foregoing, it is hereby ORDERED that:

1. The Tokai Defendants' Motion to Dismiss (Docket No. 81) is ALLOWED.

2. The Underwriter Defendants' Motion to Dismiss (Docket No. 85) is ALLOWED.

3. This case is DISMISSED.

UNITED STATES DISTRICT JUDGE